



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0220]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0557. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Pharmacogenomic Data Submissions--(OMB Control Number 0910-0557)--Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologics license applications (BLAs) on what pharmacogenomic data should be submitted to the Agency during the drug development process. Sponsors holding, and applicants submitting, INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the Agency data relevant to drug safety and efficacy (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910-0014 (part 312, INDs); 0910-0001 (part 314, NDAs and annual reports); and 0910-0338 (part 601, BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well-developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the Agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with these submissions over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately four sponsors will submit approximately one VGDS each, and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

In the Federal Register of February 6, 2014 (79 FR 7198), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Voluntary Genomic Data Submissions	4	1	4	50	200

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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